REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application are respectfully requested in light of the amendments above and the comments which follow.

As correctly noted in the Office Action summary, claims 1-16 and 52-68 were pending. By the present response, claim 60 has been canceled, claims 52-59 and 61-68 have been amended, and claims 69-83 have been added. Therefore, upon entry of the present response, claims 1-16, 52-59 and 61-83 are pending await further consideration on the merits.

Support for the foregoing claim amendments can be found at least at the following locations in the original disclosure: original claims 1-16; Figures 1A-5C; page 5, line 29 - page 6, line 5; page 6, lines 6-21; page 12, lines 4-13; and page 13, line 25 - page 14, line 3.

CLAIM REJECTIONS UNDER 35 U.S.C. §112

Claims 60 and 62-66 stand rejected under 35 U.S.C. §112, first paragraph on the grounds set forth on pages 2-3 of the Official Action.

Nothing in 35 U.S.C. §112 requires the claims to correspond to the specific embodiments described in the specification. As a general rule, claims can cover more than the specific embodiments illustrated in the disclosure, if the prior art permits. In re Newton, 414 F.2d 1400, 1406, 163 USPQ 34, 39 (CCPA 1969). Therefore, 35 U.S.C. §112, first paragraph is still satisfied even the claims cover more than the preferred

embodiments expressly described in the specification. In re Smythe, 480 F.2d 1376, 178 USPQ 279, 284 (CCPA 1973).

Claims 52-66 stand rejected under 35 U.S.C. §112, second paragraph on the grounds set forth on page 3 of the Official Action. In particular, claims 52 and 60 stand rejected on the grounds that these claims are iIncomplete for omitting essential elements.

Nothing in 35 U.S.C. §112, second paragraph requires a patent applicant to assert every conceivable feature associated with an invention set forth in the specification within the claims in order to satisfy the definiteness requirements of the statute.

The claim language is not required to enable one of ordinary skill in the art to make and use the invention, or satisfy the written description requirement, in order to satisfy the definiteness requirements of 35 U.S.C. §112, second paragraph, Rather, this is the purpose of the specification. In this regard, the Federal Circuit has held that:

> [I]t is entirely consistent with the claim definiteness requirements of the second ¶ of §112, to present "sub-combination" claims, drawn to only one aspect or combination of elements of an invention . . . Karl Zeiss Stiftung v. Renishaw PLC, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991).

Further, in this regard, the Federal Circuit has rejected arguments that claims are indefinite under 35 U.S.C. second paragraph because they did not describe a "workable invention". Miles Laboratories, Inc. v. Shandon, Inc., 997 F.2d 870, 27 USPQ2d 1123 (Fed. Cir. 1993, cert. denied, 510 U.S. 1100 (1994) (The above argument "is irrelevant to definiteness under §112, ¶2. The invention's operability may say nothing about a skilled artisans understanding of the bounds of the claim.")

Moreover, by the present response, these claims no longer recite an electrochemical test device. Therefore, it is no longer necessary to include electrodes and a reagent to "complete" an electrochemical test device.

For at least the reasons noted above, the rejection is improper and should be withdrawn.

CLAIM REJECTIONS UNDER 35 U.S.C. §103(a)

Claims 1-16 and 52-66 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,437,999 to Diebold et al. (hereafter *"Diebold et al."*) in view of U.S. Patent No. 4,217,374 to Ovshinsky et al. (hereafter *"Ovshinsky et al."*) on the grounds set forth on page four of the Official Action. For at least the reasons noted below, the rejection should be withdrawn.

The present invention is directed to a test device The advantages of the present invention over conventional test devices are discussed in previous responses.

A device instructed according to the principles of the present invention is embodied in claim 1. Such a device includes:

> *1. (a) a single substrate, the single substrate comprising a non-conductive coating affixed to one side of a flexible material;*
> *(b) a working electrode comprising an amorphous semiconductor material affixed to the non-conductive coating, said working electrode having a first electrode area, a first lead and a first contact pad;*
> *(c) a counter electrode comprising an amorphous semiconductor material affixed to the non-conductive coating, said counter electrode having a second electrode area, a second lead and a second contact pad; and*

(d) a reagent capable of reacting with the analyte to produce a measurable change in potential which can be correlated to the presence or concentration of the analyte in the fluid sample, said reagent overlaying at least a portion of the first electrode area of the working electrode.

A device constructed according to a further aspect of the present invention is embodied, for example, in amended claim 52. Such a device includes:

52. A device comprising:
a single substrate, the single substrate being of sufficient flexibility to undergo roll-type processing, the single substrate comprising a flexible metallic material;
a non-conductive, surface morphology-improving coating affixed to a surface of the single substrate; and
an amorphous semiconductor material layer affixed to the non-conductive coating.

A device constructed according to a yet another aspect of the present invention is embodied, for example, in claim 61. Such a device includes:

61. A device comprising:
a single substrate, the single substrate being of sufficient flexibility to undergo roll-type processing, the single substrate comprising an annealed, preshrunk polymeric material;
a surface morphology-improving coating affixed to a surface of the single substrate, wherein the coating is a non-conductive coating; and
an amorphous semiconductor material affixed to the coating.

A device constructed according to a yet another aspect of the present invention is embodied, for example, in claim 69. Such a device includes:

69. An electrochemical test device for determining the presence or concentration of an analyte in an aqueous fluid sample, said electrochemical test device comprising:

a substrate, the substrate consisting of a single layer of flexible material, the flexible material having sufficient flexibility to undergo roll-type processing;

a non-conductive coating affixed to one side of the substrate;

a working electrode comprising an amorphous semiconductor material affixed to the non-conductive coating, said working electrode having a first electrode area, a first lead and a first contact pad;

a counter electrode comprising an amorphous semiconductor material affixed to the non-conductive coating, said counter electrode having a second electrode area, a second lead and a second contact pad; and

a reagent capable of reacting with the analyte to produce a measurable change in potential which can be correlated to the presence or concentration of the analyte in the fluid sample, said reagent overlaying at least a portion of the first electrode area of the working electrode.

A device constructed according to a yet another aspect of the present invention is embodied, for example, in claim 77. Such a device includes:

77. An electrochemical test device for determining the presence or concentration of an analyte in an aqueous fluid sample, said electrochemical test device comprising:

a single substrate, the single substrate comprising a layer of flexible material, the flexible material having sufficient flexibility to undergo roll-type processing;

a non-conductive coating affixed to a side of the single substrate, the non-conductive coating having sufficient thickness to fill surface valleys of the single substrate thereby providing improved surface flatness relative to the substrate;

a working electrode comprising an amorphous semiconductor material affixed to the non-conductive coating, said working electrode having a first electrode area, a first lead and a first contact pad;

a counter electrode comprising an amorphous semiconductor material affixed to the non-conductive coating, said counter electrode having a second electrode area, a second lead and a second contact pad; and

a reagent capable of reacting with the analyte to produce a measurable change in potential which can be

correlated to the presence or concentration of the analyte in the fluid sample, said reagent overlaying at least a portion of the first electrode area of the working electrode.

It is asserted in the Official Action that *Diebold et al.* discloses all features recited in the above-mentioned claims, except for the recited amorphous semiconductor material. This assertion, especially as it would be applied to claims 1, 52, 61, 69 and 77 is traversed.

It is asserted in the Official Action that column 5, lines 62-67 and column 6, lines 35-39 disclose the construction of the claimed invention. However, the embodiment described in column 5 and 6 of *Diebold et al.* is clearly distinguishable from the construction recited in amended claims 1, 52 and 60. First, the embodiment described in columns 5 and 6 clearly instructs the deposition of an electrically conducting material directly onto to the substrate surface, "thus facilitating a less-expensive, semicontinuous production method." (See, e.g.-column 5, lines 59-61.) By contrast, claims 1, 52, 61, 69 and 77 require that the electrically conducting material be deposited, not directly upon the substrate, but upon an intervening coating. Secondly, the device described in columns 5 and 6 of *Diebold et al.* also includes a "first insulating substrate 13" in addition to a "second insulating substrate 14." (See, e.g.-column 5, line 64 and column 6, line 17.) Therefore, the device described in columns 5 and 6 of *Diebold et al.* clearly does not disclose a device having both a single substrate and a nonconductive coating as required by amended claims 1, 52, 61, 69 and 77.

It is further asserted on page 4 of the Official Action, that *Diebold et al.* discloses a thin anchor layer deposited on the substrate to increase adhesion between the electrical conducting material and the thin substrate. Column 3, lines 58-65 are cited in support of

the above assertion. *Diebold et al.* discloses an optional thin anchor layer of "chromium, titanium, or other suitable material (not shown in Fig. 1)." It is further asserted on page 4 of the Official Action that "it would have been clear to one of ordinary skill in the art that such thin anchor layer usually involve surface morphology-improving." This assertion is respectfully traversed.

First, it is important to recognize that the embodiment described in columns 3-4 of *Diebold et al.* describe an embodiment in which a device is formed which does not include a single substrate. To the contrary, *Diebold et al.* clearly teaches laminating a second rigid substrate member to the first substrate member (see, e.g. - column 4, lines 22-32 ("metallized thin support material 3 is then laminated . . . to first insulating substrate 4")).

Second, since *Diebold et al.* clearly fails to expressly disclose that the "thin anchor layer" is capable of improving the surface morphology of the substrate material 3, it is clear that the Examiner relies upon the principle of inherency to supply this missing teaching. However, it must be recognized that in order to establish that a claim limitation, which is not expressly disclosed in the prior art, is none the less inherent, it must be shown that the missing element must necessarily be present in the prior art device. In re King, 801 F.2d 1324, 231 USPQ 136, 138 (Fed. Cir. 1986). The CCPA has stated the principle another way:

> [I]nherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

The grounds of rejection clearly fail to contain any explanation as to why the generically reference "thin anchor layer" of *Diebold et al.* must necessarily satisfy the requirements of the presently claimed invention. To the contrary, as discussed, for example, on page 13 of the present specification, a surface-morphology coating must be provided with a certain thickness in order to improve the surface morphology of the substrate material (see, e.g. - page 13, lines 28-31). Nowhere does *Diebold et al.* disclose, or even suggest, application of the thin anchor layer in this manner. Thus, the teachings of *Diebold et al.* are clearly insufficient to satisfy at least this aspect of the presently claimed invention.

Third, it is further asserted on page 4 of the Official Action that "surface roughening step" discussed in column 4 of *Diebold et al.* satisfies the recited "surface morphology-improving" limitation of the presently claimed invention. This assertion is respectfully traversed. Initially, it should be recognized that claim language is not to be interpreted in a vacuum, but rather in light of the specification and meanings that would be attributed to the claim language, in light of the specification, by those of ordinary skill in the art. When taken in the proper context, the recited "surface-morphology improving" coating of the present invention clearly references a coating which improves surface flatness relative to the surface of the substrate (see, e.g. - page 13, lines 27-31). Thus, the referenced "surface roughening" step of *Diebold et al.* clearly does not "improve" the surface morphology coating as required by the presently claimed invention.

Therefore, for at least the reasons noted above, *Diebold et al.* fails to disclose or suggest the invention as recited by claims 1, 52, 61, 69 and 77.

Ovshinsky et al. is applied as teaching use of an amorphous semiconductor material. However, *Ovshinsky et al.* does nothing to cure the above-noted deficiencies noted in connection with *Diebold et al.* Moreover, even if the teachings of *Ovshinsky et al.* were applied, one of ordinary skill in the art would have been led even further away from the presently claimed invention.

It is important to keep in mind that the teachings of prior art references must be considered as a whole. It is clearly improper to pick and choose from among the various teachings contained in the prior art reference, using applicants' own disclosure as a roadmap, in an attempt to reconstruct the prior art to meet the requirements of a claimed invention.

Ovshinsky et al. teaches the development of a semiconductor film for such applications as the construction of **solar cells**. Therefore, one of ordinary skill in the art would not have turned to *Ovshinsky et al.* in an attempt to modify the teachings of *Diebold et al.*

Moreover, *Ovshinsky et al.* clearly teaches application of an amorphous semiconductor material to a conductive surface, and not to a non-conductive coating as required by claims 1, 52 and 60. Therefore, even if one of ordinary skill in the art were to apply *Ovshinsky et al.*, an objective application of the teachings of the reference would have taught away from the claimed amorphous semiconductor material applied to a non-conductive coating.

For at least the reasons noted above, the rejection is improper and should be withdrawn.

The remaining claims not expressly mentioned above depend either directly or indirectly upon claims 1, 52, 61, 69, or 77. Thus, these claims are also distinguishable over the applied prior art references for at least the same reasons noted above.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is earnestly solicited. Should the Examiner feel that any issues remain, it is requested that the undersigned by contacted so that any such issues may be adequately addressed and prosecution of the instant application expedited.

Respectfully submitted,

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Date: April 4, 2001

Attachment to Amendment Pursuant to 37 C.F.R. §1.116 dated April 4, 2001

Marked-up Claims 52-59 and 61-68

52. (Twice Amended) A [An electrochemical testing] device comprising:

a single substrate, the single substrate being of sufficient flexibility to undergo roll-type processing, the single substrate comprising a flexible metallic material;

a non-conductive, surface morphology-improving coating affixed to a surface of the single substrate; and

an amorphous semiconductor material layer affixed to the non-conductive coating.

53. (Amended) The [electrochemical test] device of claim 52, wherein the substrate has a thickness of 0.0005 - 0.005 inches.

54. (Amended) The [electrochemical test] device of claim 53, wherein the metallic material comprises aluminum.

55. (Amended) The [electrochemical test] device of claim 52, wherein the coating has a thickness less than about 0.005 inches.

56. (Amended) The [electrochemical test] device of claim 55, wherein the coating comprises an epoxy coating.

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Marked-up Claims 52-59 and 61-68

57. (Amended) The [electrochemical test] device of claim 52, wherein the semiconductor material comprises amorphous silicon oxide.

58. (Amended) The [electrochemical test] device of claim 57, wherein the amorphous silicon oxide is doped with an ion to increase conductivity.

59. (Amended) The [electrochemical test] device of claim 52, wherein the semiconductor material layer has a thickness of 1 - 5 microns.

61. (Amended) A device [The electrochemical test device of claim 60,] comprising:

a single substrate, the single substrate being of sufficient flexibility to undergo roll-type processing, the single substrate comprising an annealed, preshrunk polymeric material;

a surface morphology-improving coating affixed to a surface of the single substrate, wherein the coating is a non-conductive coating; and

an amorphous semiconductor material affixed to the coating.

62. (Amended) The [electrochemical test] device of claim [60] 61, wherein the polymeric material comprises one of a polyester, polycarbonate, and polyimide material.

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Marked-up Claims 52-59 and 61-68

63. (Amended) The [electrochemical test] device of claim [60] 61, wherein the coating has a thickness less than about 0.005 inches.

64. (Amended) The [electrochemical test] device of claim [60] 61, wherein the semiconductor material comprises amorphous silicon oxide.

65. (Amended) The [electrochemical test] device of claim 64, wherein the amorphous silicon oxide is doped with an ion to increase conductivity.

66. (Amended) The [electrochemical test] device of claim [60] 61, wherein the semiconductor material layer has a thickness of 1 - 5 microns.

67. (Amended) The [electrochemical test] device of claim 52, wherein the device comprises an electrochemical testing device, the device further comprising a reagent capable of reacting with an analyte to produce a measurable change in potential, and at least one electrode formed on the surface coating.

68. (Amended) The [electrochemical test] device of claim [60] 61, wherein the device comprises an electrochemical testing device, the device further comprising a reagent

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Marked-up Claims 52-59 and 61-68

capable of reacting with an analyte to produce a measurable change in potential, and at least one electrode formed on the surface coating.